

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ALLERGAN, INC.,

Plaintiff,

v.

LUPIN LTD. and LUPIN
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 2:11-CV-530

Jury Trial Demanded

ALLERGAN INC.'S COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendants Lupin Ltd. (“Lupin Ltd.”) and Lupin Pharmaceuticals, Inc. (“Lupin Pharmaceuticals”) (collectively “Lupin” or “Defendants”), Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”), by its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent No. 8,008,338 (“the ‘338 patent”) under 35 U.S.C. §§ 271(a), (b), and (e)(2) that arises out of Lupin’s filing of Abbreviated New Drug Application (“ANDA”) No. 20-2698 with the U.S. Food and Drug Administration (“FDA”).

The Parties

2. Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including Allergan’s product at issue in this case, ACULAR

LS®. Allergan employs approximately 600 individuals in Texas, more than in any other U.S. state except California.

4. On information and belief, Lupin Ltd. is a corporation organized under the laws of India with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India.

5. On information and belief, Lupin Ltd. is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing generic drugs throughout the United States, including in this judicial district, through operating subsidiaries, including Lupin Pharmaceuticals.

6. On information and belief, Lupin Pharmaceuticals, a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the Commonwealth of Virginia, with a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

7. On information and belief, Lupin Pharmaceuticals is in the business of offering for sale and selling generic drugs throughout the United States, including in this judicial district, and regularly acts as Lupin Ltd.'s U.S. agent on filings with the FDA.

8. On information and belief, and consistent with their prior practice, Lupin Pharmaceuticals is the U.S. agent for Lupin Ltd.'s ANDA No. 20-2698. Lupin Pharmaceuticals has admitted to being Lupin Ltd.'s U.S. agent for ANDAs in multiple actions, including, among others, *Astrazeneca AB et al. v. Lupin Ltd. and Lupin Pharmaceuticals Inc.*, Civil Action No. 3:11-cv-4275-JAP-DEA (D.N.J.). On information and belief, and consistent with their prior practice, Lupin Ltd. and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA

No. 20-2698. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals actively participated in the preparation of ANDA No. 20-2698 and both entities submitted ANDA No. 20-2698 to the FDA.

9. On information and belief, and consistent with their prior practice, following FDA approval of ANDA No. 20-2698, Lupin Ltd. and Lupin Pharmaceuticals will act in concert to distribute and sell Lupin's proposed generic product, ketorolac tromethamine ophthalmic solution, 0.4%, throughout the United States, including in Texas. On information and belief, following FDA approval of ANDA 20-2698, Lupin Ltd. and Lupin Pharmaceuticals know and intend that Lupin's proposed ketorolac tromethamine ophthalmic solution, 0.4% will be distributed and sold in the United States, including in Texas.

Jurisdiction and Venue

10. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over the Defendants by virtue of their systematic and continuous contacts with this jurisdiction, as alleged herein.

12. Specifically, this Court has personal jurisdiction over the Defendants because they regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

13. On information and belief, Lupin Pharmaceuticals is registered to do business in Texas. On information and belief, Lupin Ltd. does business in Texas through Lupin Pharmaceuticals, its wholly-owned subsidiary and agent.

14. On information and belief, Lupin Pharmaceuticals is a licensed wholesale distributor of prescription drugs in Texas, and sells at least twenty-eight products in this judicial district.

15. On information and belief, during the past twelve months, Lupin Ltd., through its agent Lupin Pharmaceuticals, has sold approximately \$1.4 billion of products in Texas, at least approximately \$75 million of which were sold in this judicial district.

16. On information and belief, during the past thirty-six months, Lupin Ltd., through its agent Lupin Pharmaceuticals, has sold at least approximately \$3.0 billion of products in Texas, at least approximately \$165 million of which were sold in this judicial district.

17. On information and belief, various Lupin products appear on the Formulary Index of the Texas CHIP/Medicaid Vendor Drug Program, which provides services for over 4,000 Texas pharmacies.

18. On information and belief, Lupin products appear on the Preferred Drug List for the Texas Medicaid program and are available to the millions of Texans in this judicial district and throughout the State who participate in the Texas Medicaid program.

19. On information and belief, Lupin has entered into arrangements with Texas entities to have its products appear on the formulary list of BlueCross BlueShield Texas, a major managed care and health plan.

20. On information and belief, Lupin has authorized numerous customers in Texas to distribute both Lupin branded and generic products, including AmerisourceBergen Drug Corp., Cardinal Health, Inc., Caremark LLC, McKesson Corp., MWI Veterinary Supply Inc., NLS Animal Health, and Walgreen Co.

21. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Background

22. The '338 patent, entitled "Ketorolac Tromethamine Compositions For Treating Or Preventing Ocular Pain," issued to Christopher A. Muller, Janet K. Cheetham, Teresa H. Kuan and David F. Power on August 30, 2011. A copy of the '338 patent is attached to this complaint as Exhibit A.

23. Allergan, as assignee, owns the entire right, title, and interest in the '338 patent.

24. Allergan is the holder of an approved New Drug Application ("NDA") No. 21-528 for ketorolac tromethamine ophthalmic solution, 0.4% sold under the ACULAR LS® trademark.

25. In conjunction with that NDA, Allergan has listed with the FDA the '338 patent that covers the approved formulation of ACULAR LS®. The FDA has published the '338 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

26. ACULAR LS® is covered by at least one claim of the '338 patent.

27. On November 18, 2011, Plaintiff received a letter, dated November 17, 2011, signed on behalf of Lupin Ltd. by William A. Rakoczy, outside counsel for Lupin Ltd.

28. The November 17, 2011 letter stated that Lupin Ltd. had submitted, and the FDA had received, an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of ketorolac tromethamine ophthalmic solution, 0.4%, a generic version of Allergan's ACULAR LS® product, prior to expiration of the '338 patent. The ANDA Number for this application is 20-2698.

29. On information and belief, Lupin Pharmaceuticals is designated as Lupin Ltd.'s U.S. agent on ANDA No. 20-2698, as it has been on numerous ANDAs in the past.

30. Lupin Ltd.'s November 17, 2011 letter stated that the '338 patent is invalid and that claims 6-9 of the '338 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of Lupin's proposed ketorolac tromethamine ophthalmic solution, 0.4%.

31. Attached to the November 17, 2011 letter was a statement of the factual and legal bases for Lupin Ltd.'s certification under 21 CFR § 314.95 that the '338 patent is invalid and that claims 6-9 of the '338 patent will not be infringed by the manufacture, use, importation, sale, or offer for sale of Lupin's proposed ketorolac tromethamine ophthalmic solution, 0.4%.

32. In filing ANDA No. 20-2698, Lupin Ltd. and Lupin Pharmaceuticals have requested the FDA's approval to market a generic version of Allergan's ACULAR LS® product throughout the United States, including in Texas.

33. On information and belief, following FDA approval of ANDA No. 20-2698, Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, will sell the approved generic version of Allergan's ACULAR LS® product throughout the United States, including in Texas.

Count I

(Infringement of the '338 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Ketorolac Tromethamine Ophthalmic Solution, 0.4%)

34. Paragraphs 1 to 33 are incorporated herein as set forth above.

35. Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, submitted ANDA No. 20-2698 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic ketorolac tromethamine ophthalmic solution, 0.4% throughout the United States. By submitting

this application, Lupin Ltd. and Lupin Pharmaceuticals committed an act of infringement of the '338 patent under 35 U.S.C. § 271(e)(2)(A).

36. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will constitute an act of direct infringement of the '338 patent.

37. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals became aware of the '338 patent no later than the date on which they jointly submitted ANDA No. 20-2698 to the FDA, in which they identified the '338 patent as one of the patents covering the approved formulation of ACULAR LS®.

38. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will actively induce the actual infringement of the '338 patent.

39. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals know or should know that their proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will be especially made or especially adapted for use in an infringement of the '338 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will actively contribute to the actual infringement of the '338 patent.

40. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic ketorolac tromethamine ophthalmic solution, 0.4% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count II

**(Declaratory Judgment of Infringement of the ‘338 Patent
Under 35 U.S.C. § 271(a) and/or (b) by Lupin’s Proposed
Generic Ketorolac Tromethamine Ophthalmic Solution, 0.4%)**

41. Paragraphs 1 to 40 are incorporated herein as set forth above.

42. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin’s proposed generic ketorolac tromethamine ophthalmic solution, 0.4% immediately and imminently upon approval of ANDA No. 20-2698.

43. The manufacture, use, offer for sale, sale, and/or importation of Lupin’s proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will constitute an act of direct infringement of the ‘338 patent.

44. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals intend to, and will, actively induce infringement of the ‘338 patent when ANDA No. 20-2698 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

45. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals became aware of the ‘338 patent no later than the date on which they jointly submitted ANDA No. 20-2698 to the FDA, in which they identified the ‘338 patent as one of the patents covering the approved formulation of ACULAR LS®.

46. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals know or should know that their commercial manufacture, use, offer for sale, and/or importation of their proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will actively induce the actual infringement of the ‘338 patent.

47. The foregoing actions by Lupin Ltd. and Lupin Pharmaceuticals constitute and/or will constitute infringement of the '338 patent and active inducement of infringement of the '338 patent.

48. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Allergan on the one hand and Lupin Ltd. and Lupin Pharmaceuticals on the other hand regarding Lupin Ltd. and Lupin Pharmaceuticals' infringement of the '338 patent and active inducement of infringement of the '338 patent.

49. Allergan is entitled to a judgment declaring that the foregoing actions by Lupin Ltd. and Lupin Pharmaceuticals constitute and/or will constitute infringement of the '338 patent and active inducement of infringement of the '338 patent.

50. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals have acted with full knowledge of the '338 patent and without a reasonable basis for believing that they would not be liable for infringing the '338 patent and actively inducing the infringement of the '338 patent.

51. Unless Lupin Ltd. and Lupin Pharmaceuticals are enjoined from infringing the '338 patent and actively inducing infringement of the '338 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Jury Trial Demand

Pursuant to Federal Rule of Civil Procedure 38(b), Allergan hereby demands a trial by jury of all issues so triable.

Prayer for Relief

Allergan respectfully prays for the following relief:

a. That judgment be entered that Lupin Ltd. and Lupin Pharmaceuticals have infringed the '338 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-2698 under section 505(j) of the FDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Lupin's proposed generic ketorolac tromethamine ophthalmic solution, 0.4% will constitute an act of infringement of the '338 patent;

b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Lupin's ANDA No. 20-2698 shall be a date which is not earlier than the expiration date of the '338 patent, as extended by any applicable period of exclusivity;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Lupin Ltd. and Lupin Pharmaceuticals, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer of sale, or sale within the United States, or importation into the United States, of any drug product covered by the '338 patent;

d. That, if Lupin Ltd. or Lupin Pharmaceuticals attempts to engage in the commercial manufacture, use, offer of sale, sale, or importation of Lupin's generic product disclosed in their ANDA No. 20-2698 prior to the expiration of the '338 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. That, if Lupin Ltd. or Lupin Pharmaceuticals attempts to engage in the commercial manufacture, use, offer for sale, sale or importation of Lupin's generic product disclosed in their ANDA No. 20-2698 prior to the expiration of the '338 patent, as extended by any applicable period of exclusivity, judgment be entered awarding Allergan damages resulting

from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

f. That judgment be entered declaring that Lupin Ltd. and Lupin Pharmaceuticals will infringe the '338 patent and will actively induce infringement of the '338 patent if and when they engage in the commercial manufacture, use, offer for sale, sale, or importation of Lupin's generic product disclosed in their ANDA No. 20-2698 prior to the expiration of the '338 patent, as extended by any applicable period of exclusivity;

g. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs;

h. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales be entered; and

i. That this Court award such other and further relief as it may deem just and proper.

Dated: December 30, 2011

Respectfully submitted,

By: /s/ Wesley Hill

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